Look Beyond Financial Conflicts of Interest in Evaluating Industry–Academia Collaborations in Burden-of-Illness and Outcomes Research Studies in Dermatology

Mary M. Prendergast,* William Abramovits,† Mark Boguniewicz,‡ Mark Lebwohl,§ Michael Tokar,¶ and Kuo B. Tong¶

*Fujisawa Healthcare, Inc., Deerfield, Illinois; †Baylor University Medical Center and University of Texas Southwestern School of Medicine, Dallas, Texas; ‡National Jewish Medical and Research Center and University of Colorado School of Medicine, Denver, Colorado; §The Mount Sinai School of Medicine of New York University, New York, New York; ¶Quorum Consulting, Inc., San Francisco, California

Financial relationships exist among industry, scientific investigators, and academic medical centers. These relationships can foster research in the basic sciences, clinical trials, health economics evaluations, and other outcomes assessment studies. To govern the conduct of burden-of-illness and outcomes research studies involving collaborations between industry and academia, we propose voluntary standards related to: 1) the development of and adherence to standards for research conduct and reporting; 2) disclosure, discussion, and management of potential impacts of financial conflicts of interest; and 3) transparency in research methods and open access to study results.

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Biomedical researchers in the United States and from the international community are focusing increasingly on relationships between industry and academia, and their effects on the conduct and results of research studies (Als-Nielsen *et al*, 2003; Baird, 2003; Danforth *et al*, 2001). Much of the debate has centered around financial relationships and disclosure between individual researchers and industry sponsors, and the effect of conflicts of interest on biases in conducting research and reporting results (Drazen and Curfman, 2002). In 2001, the International Committee of Medical Journal Editors modified their requirements for submitted manuscripts specifically to address how conflicts of interest may erode the trust in research publications (Davidoff *et al*, 2001).

Studies report not only widespread financial relationships but also associations between industry sponsorship and pro-industry conclusions (Bekelman *et al*, 2003; Lexchin *et al*, 2003). Some studies suggest that about one in four academic investigators in biomedical research receives funding from industry (Bekelman *et al*, 2003). Other studies report that two-thirds of academic institutions maintain financial relationships with venture entities that sponsor faculty research (Pressman, 1999).

Concerns about research funding and collaborations can extend beyond the realm of traditional clinical research, namely studies that focus primarily on safety and efficacy endpoints. They can also be applied to evaluations of outcomes research studies and studies examining the burden of illness.

Although we recognize perceived and real conflicts involved with industry–academia partnerships in clinical and outcomes research studies, and the need to minimize biases in such research endeavors, we believe that study results should be evaluated based on the quality of the research, the strength of the analyses, and the reproducibility of the results. Therefore, we propose standards in the development and reporting of outcomes and burden-of-illness studies in dermatology related to: (1) conducting outcomes studies; (2) managing financial conflicts of interest; and (3) promoting research transparency for organizations and individuals.

How Much Focus Should There Be on Financial Conflict of Interest?

Collaborations among industry, government, and academia are widespread, and represent relationships that are encouraged by government to foster research, development, and innovation (Bayh-Dole Act, 1980). These relationships can accelerate the development of new technologies to clinical practice, leading to significant health improvements. At the same time, they raise ethical concerns regarding research motives and conduct (Martin and Reynolds, 2002). Johns *et al* (2003) have hypothesized that economic partnerships between industry and academia erode the public trust in academic institutions and the entire research enterprise.

"Positive" publication bias, that is, the publication of study results demonstrating improvements in outcomes of newer, experimental therapies relative to control groups, is not a phenomenon limited to industry-sponsored research

(Kjaergard and Als-Nielsen, 2002). It has been widely reported that studies with positive results are more likely to be published in biomedical journals than are studies with negative results (Callaham *et al*, 1998). In an evaluation of emergency medicine studies presented as abstracts, and subsequently published as manuscripts, Callaham and colleagues found bias evident when studies were submitted for consideration. This was amplified further in the selection of abstracts for both presentation and publication, neither of which was strongly related to study design or quality (Callaham *et al*, 1998). Therefore, researchers, authors, reviewers, and editors all play a role in publication bias.

We believe that the debate surrounding industry–academia relationships has centered too much around financial conflicts of interest and not enough on rigorous scrutiny of the research itself. Bekelman *et al* (2003) reported that the quality of industry-supported studies they examined was relatively strong because authors explicitly defined study outcome a priori, despite the fact that industry-sponsored research tends to yield pro-industry conclusions. Another evaluation of studies funded by industry also concluded that study quality was equivalent to non-industry-supported research (Lexchin *et al*, 2003).

We would argue that the quality of the study design and execution should be just as, if not more, important than financial conflicts to the critical evaluation of outcomes and burden-of-illness studies. To borrow from the immortal words of Martin Luther King, Jr, studies should "not be judged by the color of their skin but by the content of their character."

Industry Has a Vested Interest

There is no need to hide the fact that industry's involvement in basic, clinical, and outcomes research can be motivated by self-interest. The same could be said to be true of research sponsored by the government and academia.

When faced with these challenges, industry is being asked to take the lead in documenting the burden of disease across patient populations, patient quality of life over time, and the economic impact of changes in patient management. In many cases, industry's involvement in outcomes research fills voids in our knowledge about the impact of various diagnostic and therapeutic interventions on the healthcare system, which are not addressed through research focused on safety and efficacy as mandated by regulatory agencies (Sullivan, 2002).

We should not deny industry the right to address these critical questions, nor deny the opportunity for industry and academia to collaborate to find the appropriate answers. Instead of trying to stem the proliferation of such research activities, we believe it is more prudent to address issues openly, and establish parameters to ensure that such collaborations yield scientifically rigorous and intellectually honest results. As stated by Blank (1992) in this same journal, fiscal and ethical "issues are manageable and need not reduce the benefits to both industry and academia that are inherent in this relationship."

Standards for Industry–Academia Collaborations of Burden-of-Illness and Outcomes Research Studies in Dermatology

We propose the following voluntary standards to govern the conduct of burden-of-illness and outcomes research studies in dermatology involving collaborations between industry and academia.

Focus on quality studies that adhere to uniform standards Industry and academia jointly have a responsibility to establish and adhere to standards in conducting research and reporting results. For clinical research studies, the Consolidated Standards of Reporting Trials (CONSORT) statement conveys to the reader, in a transparent manner, why the study was undertaken, and how it was conducted and analyzed (Begg *et al*, 1996; Altman *et al*, 2001). In the outcomes and burden-of-illness arena, various authors and organizations have developed and proposed standards governing cost-of-illness, pharmacoeconomic, and quality-of-life studies (Gold *et al*, 1996; Smith, 1998; Bloom *et al*, 2001; Garrison, 2003). Additional work needs to be carried out in emerging areas of outcomes research and burden-of-illness to create standards that apply across research settings and geographies. By developing and adhering to standards, outcomes research studies can be methodologically rigorous and reported consistently.

Acknowledge and manage financial conflict of interest Recognizing the potential for conflict and bias is as important as the reporting of these relationships. Industry-sponsored collaborations are likely to be motivated by specific research questions involving commercial interests. These motivations should be disclosed and debated up front. When submitting abstracts to scientific conferences, presenting studies verbally at meetings, or preparing manuscripts for publication, researchers and investigators should provide relevant details of their financial relationships with biomedical companies (Davidoff *et al*, 2001). Disclosures can include but are not limited to: (1) consulting fees; (2) service on advisory boards; (3) ownership of equity; (4) patent royalties; (5) honorariums for lectures; (6) fees for expert testimony; and (7) research grants.

Promote transparency in research and do not restrict investigator behavior The research environment should promote open collaboration and information sharing. There should not be any prohibitions on information dissemination, or restrictions on the publication of research results regardless of their findings. Industry must maintain transparency and ensure access to data by researchers, in addition to balancing privacy, competitive, and intellectual property considerations.

Conclusion

The evaluation of the burden of illness in dermatology is at an exciting point in time. The resources available to assess the burden of illness are exceeded only by human curiosity and demands for more information. By establishing and adhering to rigorous standards, managing conflicts, and

maintaining research integrity, those in industry and academia will learn from each other and flourish in these pursuits.

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Address correspondence to: Mary M. Prendergast, Director Outcomes Research and Product Economics, Fujisawa Healthcare, Inc., Three Parkway North, Deerfield, IL 60015, USA. Email: mary_prendergast@fujisawa.com

References

Als-Nielsen B, Chen W, Gluud C, Kjaergard LL: Association of funding and conclusions in randomized drug trials: A reflection of treatment effect or adverse events? JAMA 290:921–928, 2003

Altman DG, Schulz KF, Moher D, *et al*: The revised CONSORT statement for reporting randomized trials: Explanation and elaboration. Ann Intern Med 134:663–694, 2001

Bayh-Dole Act: P.L. 96-517, Patent and Trademark Act Amendments (35 USC 200–212), 1980

Baird P: Getting it right: Industry sponsorship and medical research. CMAJ 168:1267–1269, 2003

Begg C, Cho M, Eastwood S, *et al*: Improving the quality of reporting of randomized controlled trials: The CONSORT statement. JAMA 276:637–639, 1996

Bekelman JE, Li Y, Gross CP: Scope and impact of financial conflicts of interest in biomedical research: A systematic review. JAMA 289:454–465, 2003

Blank IH: Industry-funded dermatologic research within academia in the United States: Fiscal and ethical considerations. J Invest Dermatol 98:265–268, 1992

Bloom BS, Bruno DJ, Maman DY, Jayadevappa R: Usefulness of US cost-of-illness studies in healthcare decision making. Pharmacoeconomics 19: 207–213, 2001

Callaham ML, Wears RL, Weber EJ, *et al*: Positive-outcome bias and other limitations in the outcome of research abstracts submitted to a scientific meeting. JAMA 280:254–257, 1998

Danforth W (Task Force Chair): Task Force on Financial Conflicts of Interest in Clinical Research: Protecting Subjects, Preserving Trust, Promoting Progress—Policy and Guidelines for the Oversight of Individual Financial Interests in Human Subjects Research. Washington, DC: American Association of Medical Colleges, 2001, web reference: http://www.aamc.org/members/coitf/firstreport.pdf

Davidoff F, DeAngelis CD, Drazen JM, *et al*: Sponsorship, authorship, and accountability. N Engl J Med 345:825–826, 2001

Drazen JM, Curfman GD: Financial associations of authors. N Engl J Med 346: 1901–1902, 2002

Garrison LP: The ISPOR good practice modeling principles—a sensible approach: Be transparent, be reasonable. Value Health 6:6–8, 2003

Gold M, Siegel J, Russell L, Weinstein M (eds). Cost-effectiveness in Health and Medicine. New York: Oxford University Press, 1996

Johns MM, Barnes M, Florencio PS: Restoring balance to industry–academia relationships in an era of institutional financial conflicts of interest: Promoting research while maintaining trust. JAMA 289:741–746, 2003

Kjaergard LL, Als-Nielsen B: Association between competing interests and authors' conclusions: Epidemiological study of randomised clinical trials published in the BMJ. BMJ 325:249, 2002

Lexchin J, Bero LA, Djulbegovic B, Clark O: Pharmaceutical industry sponsorship and research outcome and quality: Systematic review. BMJ 326:1167–1170, 2003

Martin JB, Reynolds TP: Academic-industrial relationships: Opportunities and pitfalls. Sci Eng Ethics 8:443–454, 2002

Pressman L: Association of University Technology Managers: Survey summary. Northbrook, IL: AUTM Licensing Survey, 1999

Smith MD (Executive Director): International Society for Pharmacoeconomics and Outcomes Research: Pharmacoeconomics: Identifying the Issues, 1998, web reference: http://www.ispor.org/workpaper/adpanel/index_.html

Sullivan S: Academy of Managed Care Pharmacy: Format for formulary Submissions Version 2, 2002, web reference: http://www.fmcpnet.org/data/resource/formatv20.pdf